ISSN: 2582-7162
Original Article

Stress Urinary Incontinence and Homoeopathy: A Randomized Controlled Study in Parous Women of Reproductive Age Group

Sangeeta Jain[1], Puneet R Shah[2], A. N. Mathur[3], Arun Phophalia[4]

[1]Head of The Department, Associate Professor, Department of Anatomy University College of Homoeopathy, Kekri, Ajmer, Rajasthan (A Constituent College of Dr. Sarvepalli Radha krishnan Rajasthan Ayurved University, Jodhpur, Rajasthan)

[2]Principal, University College of Homoeopathy, Kekri, Ajmer,Rajasthan Head of The Department, Associate Professor, Department of Physiology (A Constituent College of Dr. Sarvepalli Radhakrishnan Rajasthan Ayurved University, Jodhpur, Rajasthan

[3] President, Homoeopathy University, Saipura Sanganer, Jaipur, Rajasthan

[4] Medical Suprintendent, Dr.Girendra Pal Homoeopathic Hospital, Jaipur (Attached Hospital of Homoeoapthy University, Saipura Sanganer, Jaipur, Rajasthan)

Corresponding Author:
Dr. Sangeeta Jain, Ph.D. (Hom)
172, G-2, Gayatri Nagar- B, Maharani Farm, Durgapura, Jaipur, Rajasthan, 302018
Email: arihanthomoeo25@gmail.com

How to cite this article: Jain S, Shah P R, Mathur A. N., Phophalia Arun. Stress Urinary Incontinence and Homoeopathy: A Randomized Controlled Study in Parous Women of Reproductive Age Group. GFNPSS-IJMR 2023; 4:6: 2313-2322

Submitted: 30-May-2023; **Accepted:** 19-June-2023; **Published:** 4-July-2023

Abstract:

Introduction: The momentary increase in abdominal pressure while coughing, laughing and sneezing causes an involuntary urinary leakage, this is called as Stress Urinary Incontinence (SUI). Females are commonly sufferer because of weakening of pelvic floor muscles followed by childbirth. Regular pelvic floor exercise (PFE) can over come this problem gradually up to a certain limit but individualized Homoeopathic medicines can fasten up the improvement.

Materials and methods A prospective experimental randomized controlled study was conducted in which total 100 parous females of reproductive age group were studied. Patients were randomized into two groups to receive individualized homoeopathic medicines along with PFE (Group A; n=50) and placebo along with PFE (Group B; n=50). Patients of both groups were compared according to scores of Revised Urinary Incontinence Scale (RUIS). Baseline scores of both groups were measured and compared with the scores after 6 months follow-ups.

Results: The mean scores in Group A were lower than the mean scores of the Group B. The paired t test and independent t test showed statistically significant difference (P< .05). The most frequently indicated homoeopathic medicine was *Sepia officinalis*(*n*=20).

Conclusion: The treatment of Stress Urinary Incontinencein parous females of reproductive age group produced promising results with the use of the individualized homoeopathic medicines along with pelvic floor exercise.

Keywords: Stress urinary incontinence; parous women; individualized homoeopathy medicines; pelvic floor exercis

Introduction:

Unintentional loss of urine is known as the *Urinary incontinence* (UI). When urinary incontinence occurs on physical movement or activity causing pressure (stress) on urinary bladder- such as coughing, laughing, sneezing, running or heavy lifting resulting in leakage of urine, then it is called *Stress urinary incontinence* (SUI). Stress urinary incontinence is not related to psychological stress.[1]

Stress Urinary Incontinence (SUI) is defined as loss of urine of less than 50ml when there is increased abdominal pressure due to strain on the internal urethral orifice of the bladder, as in laughing, coughing and sneezing.[2]According to International classification of diseases (ICD) code N 39.3 SUI is a meatal urinary leakage that occurs as a result of physical activities with transient increase in abdominal pressure in the absence of detrusor muscle activity or over distended bladder.[3]

It is very common in females and seen most frequently after parturition which his followed by weakening of pelvic floormuscles.[4]Stress urinary incontinence (SUI) affects the quality of life of at least one third of women. This problem is more common in India, where women are not aware for their reproductive health problems and do not vocalize their symptoms.[5]This condition is creating a negative impact on one's physical, psychological, sexual, social and overall quality of life and incontinent women are much more likely to suffer from depression than their continentpeers.[6]This study proposed a treatment strategy based on the experience of treating this patient population by homoeopathic medicines selected after individualization along with pelvic floor exercise.

The primary aim of this study is to show the effectiveness of individualized homoeopathic medicines in cases of stress urinary incontinence in parous women of reproductive age group. The objective of the study is to compare the role of homoeopathic medicines along with pelvic floor exercise and only pelvic floor exercise in cases of stress urinary incontinence in parous women of reproductive age group according to Revised Urinary Incontinence Scale (RUIS).

Materials and methods

This experimental randomized controlled study (*Pretest-Posttest design*) was conducted at Dr. M.P.K. Homoeopathic Medical College, Hospital & Research Centre, Jaipur (a constituent college of Homoeopathy University). Sample size (100) was determined by taking into account by effectiveness of treatment and power oftest.[7] A total of 341 parous females of reproductive age group were screened (through Questionnaire for Urinary Incontinence Diagnosis (QUID),[8]outof which 100females were enrolled for the study, after taking consent, who have had pure stress urinary incontinence having baseline characteristics of involuntary urinary leakage on coughing, laughing and sneezing. Pregnant and lactating parous women of reproductive age group were excluded from the study. Women who were taking diuretics (antihypertensives, analgesics, antipsychotics, etc.) and alcoholics also were excluded. The study duration was 18 months and each case was followed by every15/30 days, till six months. Randomization was performed with allocation concealment using sequentially numbered, opaque, sealed envelopes (SNOSE)[9] without blinding. All women were divided equally and randomly into two study groups; Group A was intervened by individualized homoeopathic medicines along with pelvic floor exercise and Group B was prescribed placebo along with pelvic floor exercise.

Primary outcome in this study was the decrease in amount of urine loss during increased abdominal pressure and its assessment was done according to Revised Urinary Incontinence Scale (RUIS)[10] (pre and post test scores).The Revised Urinary Incontinence Scale (RUIS) contains 5 items drawn from the Urogenital Distress Inventory-6 (UDI-6) and the Incontinence Severity Index (ISI).[10]Data analysis was carried out by data sorting method, classification by tabulation and interpretation by histograms and pie diagrams. Data analysis was done using SPSS (Version16.0.2)[11]and excel. Statistical method, paired t test,[12] was used to compare RUIS scores before and after treatment in both Groups A and B. Independent t test[12] was also used to compare RUIS scores between both Groups A and B to see the difference after treatment. The ethical clearance was obtained from the Institutional Ethical Committee (IEC) of Homoeopathy University, Jaipur, prior to conducting the study.

Observations and Results

A total of 341 parous females of reproductive age group were screened. Female shaving urinary incontinence were 229(67.16%) in number; pure SUI was found in170 (74.24%), pure UUI was found in 6 (2.6%) and mixed incontinence was found in 53(23.14%) females. Out of 170SUI females 100 female: ut case in the study, analysis was carried

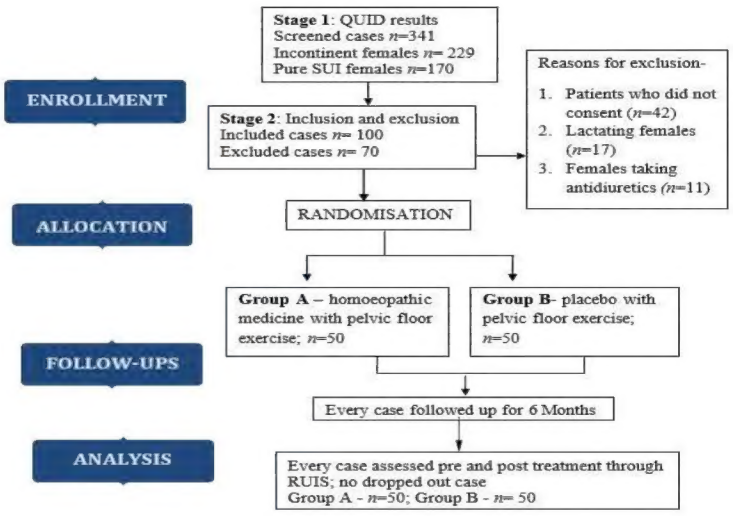

Fig. 1: CONSORT flow diagram[13] of patients included/ excluded for the study

Distribution of Study Population according to Age: Females of any age group can be affected with SUI after parturition, but in this study maximum cases (31%) were found in the age group of 36-40 years as observed in both the study groups (Fig. 2 & 3); 36% cases in group A (Fig. 2) and 26% cases in group B (Fig. 3).

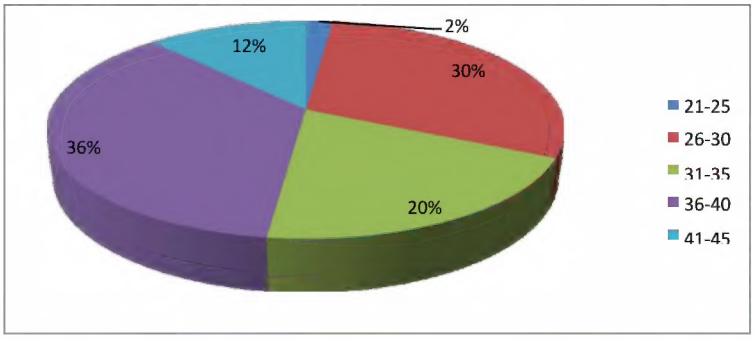

Fig.2: Distribution of Study Population according to Age in Group A:

https://doi.org/10.46376/ijmr/04.06.2023-2313-2322

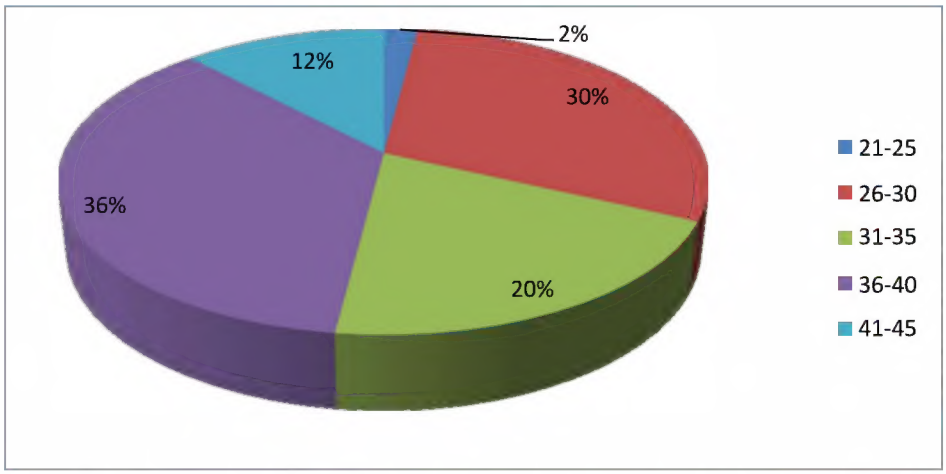

Fig. 3: Distribution of study population according to age in Group B

Distribution of Study Population according to Parity: In this study, stress urinary incontinence was found to be greatest (63%) in females of reproductive age group with parity of 2 (Fig. 6). In the Group A, 29 females with parity of 2 were found to be suffering from SUI, followed by 9 females with parity of 3, 8 females with parity of 1 and 4 females with parity of 4. In Group B, 34 females with parity of 2 were found to be suffering from SUI, followed by 8 females with parity of 1, 6 females with parity of 3 and 1-1 female each with parity of 4 and 5 were found to be suffering from SUI.

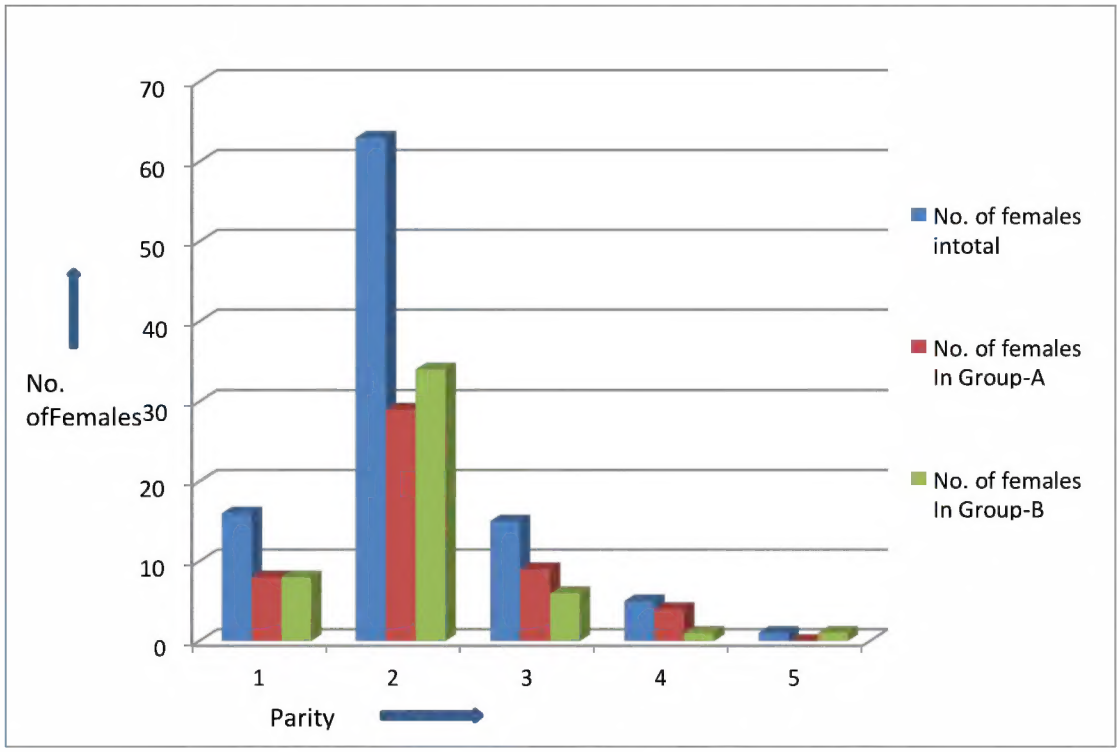

Fig. 4: Distribution of study population according to their parity

https://doi.org/10.46376/ijmr/04.06.2023-2313-2322

Presenting complaints of study population in both study groups: From the study analysis, it was observed that the presenting complaints in almost all females of both study groups were other than SUI. The complaints for which the females came to hospital were bearing down sensation, leucorrhoea, skin disorders, hair fall, fever, gastric disorders, allergic rhinitis, cough, pain abdomen, haemorrhoids, burning urination etc. there was only one patient who came for involuntary urination.

Response to homoeopathic remedies with PFE in patients of Group A: Table 1 shows the response to the homoeopathic remedies with PFE in patients of Group A and changes noticed in Scores of RUIS after treatment. Sepia officinalis was found to be most indicated medicine prescribed in 20 patients, followed by Natrum muriaticum, Pulsatilla, Nux vomica, Causticum, Sulphur and Calcarea carbonica. In Group A, 100% improvement achieved by 16 (32%) patients. Sepia officinalis showed 100% improvement in 8 patients.

Table1: Response to homoeopathic remedy with PFE in study Group A(n=50):

S. no.	Medicine given with PFE	Number ofpatients	Response to remedies in patients after treatment according to RUIS scores				
			100%	75-99%	50-74%	25-49%	<25%
1	*Sepiaofficinalis*	20	8	4	8	0	0
2	*Natrummuriaticum*	9	1	8	0	0	0
3	*Pulsatilla*	9	4	2	3	0	0
4	*Nuxvomica*	7	1	2	4	0	0
5	*Causticum*	2	0	2	0	0	0
6	*Sulphur*	2	1	1	0	0	0
7	*Calcareacarbonica*	1	1	0	0	0	0
	Total	**50**	**16**	**19**	**15**	**0**	**0**

Response to Placebo with PFE in patients of Group B: Table 2 shows the response to the placebo with PFE in patients of group B and changes noticed in scores of RUIS after treatment. Not a single patient showed 100%improvement in scores of RUIS.

Table2: Response to Placebo with PFE in study Group B (n=50):

S. no.	Medicine given with PFE	Number of patients	Response to remedies in patients after treatment according to RUIS scores				
			100%	75-99%	50-74%	25-49%	<25%
1	Placebo	50	0	3	29	26	0

Statistical tools application:

Independent test (before treatment): The results presented in Table 3 show that the value of significance level is .914 in RUIS which is greater than .05 (P > .05), hence we accepted the null hypothesis, i.e. there is no statistically significant difference between the average scores of RUIS of the two groups (Group A and Group B) before treatment which means both groups are comparable.

Table 3: Independent Samples Test-RUIS(before treatment)

Particulars	F	Sig.	t	df	Sig.(2-tailed)	Mean diff.	Std. Error diff.	95% Confidence Interval of the Difference	
								Lower	Upper
RUIS scores Gp A- Gp B(BT)	.53	.468	-.108	98	0.914	-0.04	0.37	-0.774	0.694

https://doi.org/10.46376/ijmr/04.06.2023-2313-2322

Paired t test: To analyze the changes in the scores of RUIS, paired t test was applied in both groups (Tables 4 & 5). The mean scores of RUIS reduced from 10.80 to 2.06 in Group A and from 10.84 to 5.18 in Group B. Although the changes were relatively greater in Group A, however the changes were statistically significant in both groups.

Table 4: Paired Samples Test in RUIS-Group A

Particulars	Mean	Std. Deviation	Std. Error Mean	95% Confidence Interval of the Difference		t	df	Sig.(2-tailed)
				Lower	Upper			
GpA_RUIS_BT -GpA_RUIS_AT	8.74	1.367	0.193	8.351	9.129	45.196	49	0

Taable5: Paired Samples Test in RUIS-Group B

Particulars	Mean	Std. Deviation	Std. Error Mean	95% Confidence Interval of the Difference		t	df	Sig.(2-tailed)
				Lower	Upper			
GpB_RUIS_BT- GpB_RUIS_AT	5.66	1.56	0.221	5.217	6.103	25.658	49	0

Independent test (after treatment): The scores of both groups (Group A and Group B) were compared after the treatment to assess the effect of treatment. The results presented in Table 6 show that the mean scores in Group A were lower than the mean scores of the Group B, and the difference was statistically significant. Hence, we reject the null hypothesis and accept the alternative hypothesis that there is a difference between Homoeopathic intervention and Placebo in the treatment of patients suffering from SUI. It means the homoeopathic medicines selected after individualization are effective in the treatment of stress urinary incontinence.

Table 6: Independent Samples Test-RUIS (after treatment)

Particulars	F	Sig.	t	df	Sig.(2-tailed)	Mean diff.	Std.Error diff.	95%Confidence Interval of the Difference	
								Lower	Upper
RUIS scores Gp A- Gp B(AT)	1.846	0.177	-9.292	98	0	-3.12	0.336	-3.786	-2.454

Evaluation of improvement in RUIS before and after treatment in Group A and Group B: It can be observed from Figures 5 & 6 that the changes in RUIS scores before and after treatment were relatively greater in Group A; however the changes were statistically significant in both groups. 16 females out of 50 got 100% reduction in RUIS scores in Group Abut no one in Group B.

https://doi.org/10.46376/ijmr/04.06.2023-2313-2322

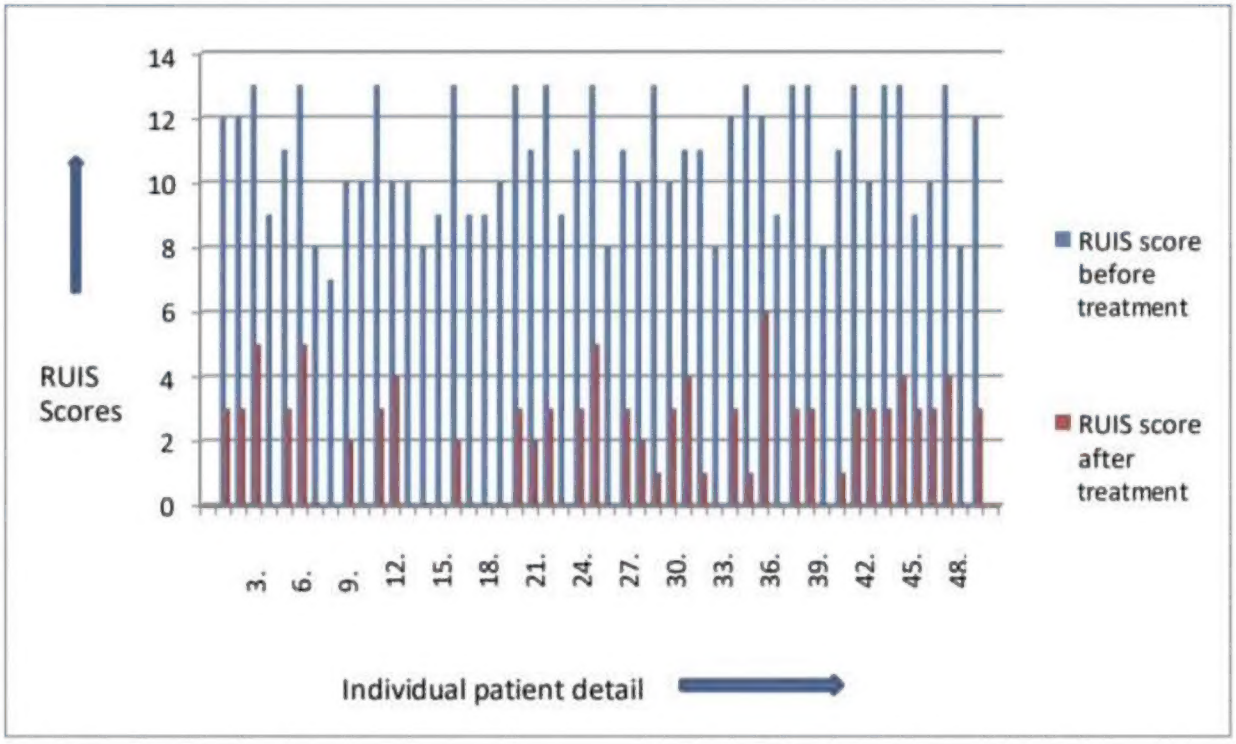

Fig. 5: Distribution of individual patient's RUIS score in Group A before and after treatment

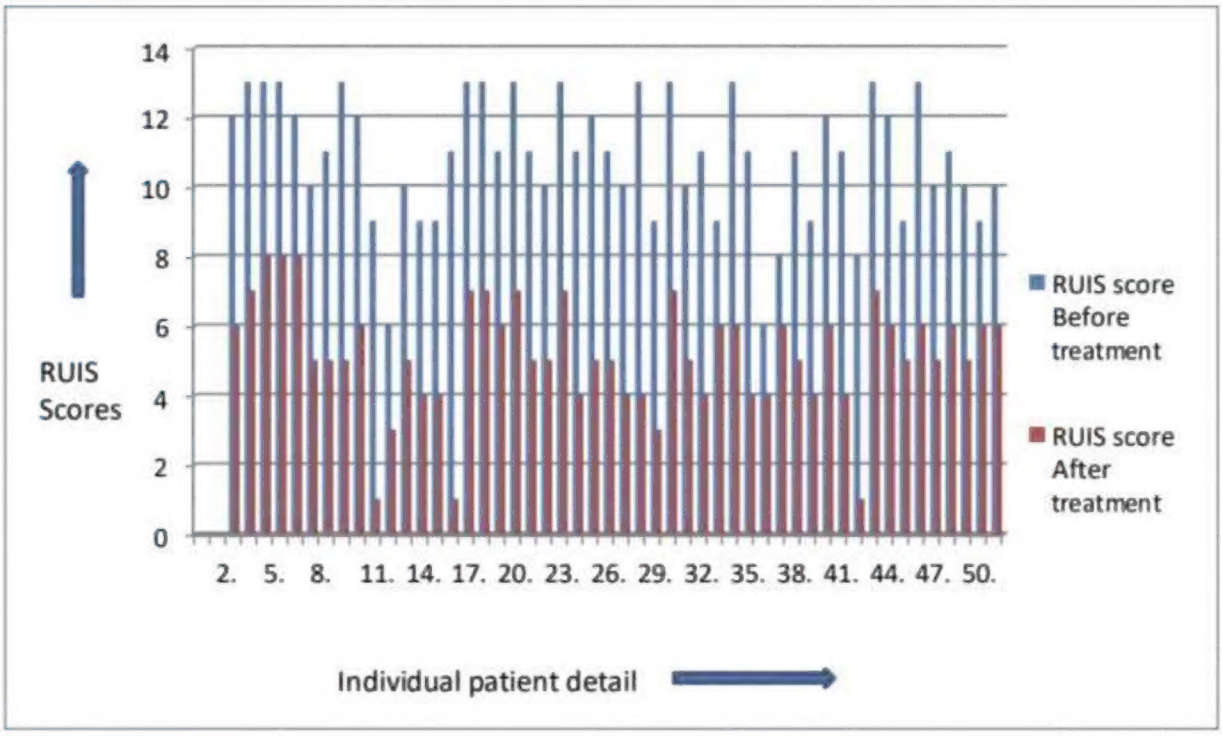

Fig. 6: Distribution of individual patient's RUIS score in Group B before and after treatment

https://doi.org/10.46376/ijmr/04.06.2023-2313-2322

Discussion:

In present study, maximum cases of SUI (31%) were found in 36-40 years of age group. Karl M Luber[14] in his review study showed similar results found by Hampel & colleagues and Thom that older women were more likely to experience urge incontinence and younger women were proportionately more likely to experience SUI. Uma Singh[15] and colleagues also reported the same statements. In this study, the females with parity of 2 showed highest incidence of SUI (63%) and it was changing towards urge incontinence as the parity increases. This is comparable to the observation of Uma Singh[15] and others who reported that incontinence is positively associated with increasing parity; differentially stress incontinence showed an increasing trend towards urge incontinence with increasing parity. The study of Karl M Luber[14] also showed that the data available regarding the influence of pregnancy and route of delivery on the pelvic floor disorders such as SUI. The parous females included in this study, came for other clinical conditions which were not directly related to urinary incontinence. They were screened for urinary incontinence and found to be stress urinary incontinent. Only one parous female directly came for urinary incontinence. Karl M Luber[14] stated that many women with SUI do not seek care for their condition; the occasional symptom of stress loss may not translate into a level of bother that qualifies as the disease of stress incontinence. Others are embarrassed to speak with a health care provider about their condition or fear that treatment will require surgery. In this study, results indicate the effectiveness of the individualized homoeopathic medicines in cases of SUI in parous females of reproductive age group. Since there are no studies of the effects of homoeopathic medicines in cases of SUI, the produced changes in this study cannot be discussed. The effects of pelvic floor exercise in patients of Group B were also remarkable, and can be compared with the study of Borello DF[16] and his friends who concluded that Pelvic-floor muscle exercise is 50-69% effective in reducing urine loss episodes in women. However, there are problems with pelvic floor exercises; improvement is more common than cure.

Statistical analysis: The baseline data (scores of RUIS) were not significantly different between Group A and Group B. At endpoint of study, 100% reduction was found in scores of RUIS in 16 (32%) females of Group A. The mean scores of RUIS reduced from 10.80 to 2.06 (95% CI 8.351, 9.129) in Group A and from 10.84 to 5.18 (95% CI 5.217, 6.103) in Group B. The scores of RUIS after treatment in Group A and Group B were compared; the mean scores in Group A were lower than the mean scores of the Group B. The paired t test and independent t test showed statistically significant difference ($P < .05$).

Conclusion: Individualized homoeopathic medicines along with PFE produced a remarkable reduction in the scores of RUIS which substantiated the potential of the homoeopathic medicines in the effective treatment of SUI. The outcomes proposed in the study were steady and permanent and achieved through conducting the clinical trial; and no adverse effect was noted during the study. Hence, this research study conclusively establishes the effectiveness of individualized homoeopathic medicines in the treatment of stress urinary incontinence in parous females of reproductive age group.

Limitations and Strength: Though it was very difficult to convince the females in beginning for the study as they came for other clinical conditions which were not directly related to urinary incontinence but the results produced showed that they were satisfied.

Future aspect: In future we can conduct this type of research on large sample size to establish the effectivity of Homoeopathic medicines in cases of stress urinary incontinence.

Acknowledgement: We acknowledge Dr. Girendra Pal sir (Chairperson of Homoeopathy University) and Dr. Chaturbhuja Nayak (former President of Homoeopathy University), for providing us a platform to conduct research in Homoeopathic science and for their constant encouragement and scientific suggestions in completing this task successfully.

Disclaimers: Not needed as the patient identity is not disclosed.

Source(s) of support in the form of grants, equipment, drugs, or all of these: Nil

A running head: *Stress Urinary Incontinence and Homoeopathy*

The number of figures and tables: Figures: 6; Tables: 6

Conflict of Interest: No

References

1. Stress incontinence [Internet] 2022 Mar 22 [updated 2022 Mar 22; cited 2023 May 26]. Available from:https://www.mayoclinic.org/diseases-conditions/stress-incontinence/symptoms-causes/syc-20355727
2. Miller-Keane Encyclopedia and Dictionary of Medicine, Nursing, and Allied Health [Internet]. 7th ed. Saunders: Elsevier; 2003. Stress urinary incontinence [cited 2018 Apr 28]. Available from: http://medical-dictionary.the free dictionary.com.
3. American Medical Association. ICD 10-CM 2017: the complete official code book. Chicago, Illinois: American Medical Association; 2016.
4. Goddard J, Turner AN. Kidney and urinary tract disease. In: Walker BR, ColledgeNR, Ralston SH, Penman ID, editors. Davidson's Principles & Practice of Medicine. 22nd ed. Edinburgh: Churchill Livingstone Elsevier; 2014.
5. Baranitharan R, Mahalakshmi V. Prevalence of type of urinary incontinence and their association with types of delivery. Indian Journal of Physiotherapy andOccupational Therapy 2009;3(4):9-12.
6. Vigod SN, Stewart DE. Major Depression in Female Urinary Incontinence. Psychosomatics 2006; 47(2): 147-51.
7. Robbins BH. Hypothesis Testing, Power, Sample Size and Confidence Intervals (Part-1) [Internet]. 2010 [updated 2010 Jun 3; cited 2017 Jan 13]. Available from: http://biostat.mc.vanderbilt.edu/wiki/pub/Main/AnesShortCourse/HypothesisTestingPart1.pdf
8. Bradley CS, Rovner ES, Morgan MA, Berlin M, Novi JM, Shea JA et al. A new questionnaire for urinary incontinence diagnosis in women: development andtesting. Am J Obstet Gynecol. 2005;192: 66–73.
9. Doig GS, Simpson F. Randomization and allocation concealment: a practical guide for researchers. Journal of Critical Care June 2005;20(2):187-191.
10. Sansoni J. Tools for Assessing and Monitoring Urinary Incontinence: The RevisedUrinary Incontinence Scale (RUIS). 2017 [cited 2017 Jan 13]. Available from:

http://www.bladderbowel.gov.au/assets/doc/ncms/Phase3InformationAndEvidence/RUISBro chure.pdf

11. SPSS [computer program]. Version 16.0.2. USA: IBM Corporation; 2015.
12. Pallant J. SPSS SURVIVAL MANUAL: A step by step guide to data analysis using SPSS for Windows. Crows Nest, Australia: Allen and Unwin Publishing Company; 2001.
13. Schulz KF, Altman DG, Moher D. CONSORT 2010 Statement: updated guidelines for reporting parallel group randomised trials. BMJ 2010; 340: c332.Luber
14. KM. The Definition, Prevalence, and Risk Factors for Stress Urinary Incontinence. Reviews in Urology 2004; 6 (3): 3–9.
15. Schulz KF, Altman DG, Moher D. CONSORT 2010 Statement: updated guidelines for reporting parallel group randomised trials. BMJ 2010; 340: c332.
16. Borello DF, Downey PA, Zyczynski HM, Rause CR. Continence and Quality-of- Life Outcomes 6 Months Following an Intensive Pelvic-Floor Muscle Exercise Program for Female Stress Urinary Incontinence: A Randomized Trial Comparing-Low and High-Frequency Maintenance Exercise. Physical Therapy 2008; 88(12):1545–53.